REMARKS/ARGUMENTS

Claims 75-92 are pending. By this Amendment, claims 75, 89 and 91 are amended, and claims 93 and 94 are canceled. Reconsideration in view of the above amendments and the following remarks is respectfully requested.

The specification was objected to as allegedly failing to disclose that the elastomeric container, in use, exerts pressure on the pharmacological solution, as previously set forth in canceled claim 94, which subject matter is now included in independent claim 75.

This objection is respectfully traversed since the original specification provides clear and unequivocal support for the claimed subject matter. For example, page 3, starting at line 16, states that "the elastomeric container, when it has been filled with a pharmacological solution exerts a pressure on the solution…".

Reconsideration and withdrawal of the objection to the specification are respectfully requested.

Claims 89 and 90 were objected to based on minor informalities. By this Amendment, claim 89 has been amended in an effort to obviate the objection.

Reconsideration and withdrawal of the objection are respectfully requested.

Claim 93 was rejected under 35 U.S.C. §112, first paragraph. This rejection is respectfully traversed since the specification provides support for this subject matter, but in an effort to advance prosecution, claim 93 has been canceled.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 75-79, 81, 82 and 89-94 were rejected under 35 U.S.C. §102(b) over Martin (U.S. Patent No. 4,976,687). This rejection is respectfully traversed.

Claim 75 recites a system for the infusion of a pharmacological solution in a patient, comprising an elastomeric container for containing a pharmacological solution and for generating a flow of said pharmacological solution from said container to a catheter insertable in the body of the patient, said elastomeric container, in use, exerting a pressure on said pharmacological solution that generates said flow, a valve arrangement to vary said flow, a command and control device operationally connected to said valve arrangement to command a pulsed actuation of said valve arrangement, said flow being determined by the number of actuations of said valve arrangement per unit time, and an infusion protocol according to which said pulsed actuation is made, said infusion protocol comprising a pre-programmed series of openings and closings of said valve arrangement with preset durations and at preset intervals of time.

Claim 75 includes the subject matter of canceled claim 94 (the elastomeric container, in use, exerting a pressure on the pharmacological solution that generates said flow) and also specifies that an infusion protocol according to which the pulse actuation is made, which infusion protocol comprises a preprogrammed series of openings and closings of the valve arrangement with preset durations and at preset intervals of time. This subject matter is supported in the original specification, e.g., see paragraph 47-62 of the published application where it is stated that preprogramming of the system for an infusion protocol is disclosed, particularly during the proceedings to set and test a new infusion protocol, when the valve 13 is calibrated.

Paragraph [0051] states "If the quantity of solution delivered by the valve 13 differs from the theoretical preset value by a quantity greater than a preset quantity the aforementioned durations and intervals are varied until the quantity of delivered solution is not different from the

theoretical amount by a quantity less than said preset quantity." It is clear that the infusion protocol that is then stored and not modifiable (paragraph [0060]), comprises a series of valve openings and closings with certain durations and intervals.

Therefore, Martin does not anticipate the subject matter of claim 75. First, in Martin the flow rate of the solution is determined on the basis of pressure signals provided to the controller in a closed loop system. The microprocessor 116 responds to the differential pressure as sensed by the two pressure transducers 114, 120 to maintain the preset flow rate. The system of claim 75 is not feed back controlled but is governed by a preprogrammed infusion protocol with a series of openings and closings on the valve arrangement.

Second, in Martin there is no explicit disclosure that the elastomeric container exerts a pressure on the pharmacological solution that generates the solution flow. Martin describes a pressurized intravenous feeding system with an elastomeric reservoir 30 containing I.V. fluid under pressure. There is no disclosure that the flow is generated by pressure exerted by the elastomeric container.

Applicants with respect emphasize that Martin fails to teach generating a flow of pharmacological solution with an elastomeric container and controlling such a flow with a preprogrammed series of openings and closings of a valve arrangement with preset durations and at preset intervals of time.

In sum, claim 75 relates to an infusion system that is suitable to be construed as an integrated system (disposable or non-disposable) which can be supplied to the user, e.g., to the patient to which the pharmacological solution is infused, in a form that is substantially ready to use. As a solution to be infused, the pump to generate the infusion flow, and the infusion control program can be integrated into the system itself. The infusion control protocol can be, for

example, directly stored in the control system, or easily connected thereto (e.g., by means of a smart card or a personal computer). The system of claim 75 helps to prevent errors that can be made by the user in setting the infusion system, as the infusion parameters have already been integrated into the system. It is noted that certain infusion protocol is associated with a certain container filled with a certain solution, whereby possible user errors, such as setting an infusion protocol which is not suitable for the type of container or solution actually used, can be further minimized.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 80-85 were rejected under 35 U.S.C. §103(a) over Martin in view Kanai (U.S. Patent No. 6,367,502). In addition, claims 86-88 were rejected under 35 U.S.C. §103(a) over Martin in view of Franetzki et al. (U.S. Patent No. 4,270,532).

These rejections are respectfully traversed at least because claims 80-85 depend either directly or indirectly from claim 75, and are patentable by virtue of that dependency in addition to the further features they recite in combination with claim 75.

Reconsideration and withdrawal of the rejection are respectfully requested.

In view of the above amendments and remarks, Applicants respectfully submit that all the claims are patentable and that the entire application is in condition for allowance.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140 under Order No. PTB-4017-41.

Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, he is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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